REMARKS

Claims 1-15 are pending. Claims 1-15 were rejected under 35 U.S.C. §112, first paragraph.

Applicants have carefully considered the points raised in the Office Action and believe that the Examiner's concerns have been addressed as described herein, thereby placing this case into condition for allowance. Reconsideration of the rejections contained in the Office Action is respectfully requested.

Rejections under 35 U.S.C. §112, first paragraph

Claims 1-15 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner contends that a person skilled in the art would not able to use the method for suppressing a respiratory syncytial virus infection in an individual by administering a composition of polynucleotide comprising an ISS without undue experimentation, considering the lack of guidance from the prior art or from the specification. Office Action, page 5. Applicant respectfully traverses this rejection.

The Examiner contends that the specification needs to show an effective treatment in alleviating a symptom of RSV by the claimed ISS sequences. The Examiner states that the "working example set forth discloses inhibition in replication of the virus in lung samples of experimental animals." The Examiner further states, "[h]owever, the results do not indicate that any of the symptoms of respiratory infection is ameliorated." Office Action, page 4.

Applicant respectfully points out that the pending claims of the application are directed to a method of suppressing an RSV infection by administering a composition comprising a polynucleotide comprising an ISS with a 5'-C, G-3' sequence and to a kit for use in the method. The specification describes suppressing viral infection "indicates any aspect of viral infection,

such as viral replication, time course of infection, amount (titer) of virus, lesions, and/or one or more symptoms is curtailed, inhibited, or reduced (in terms of severity and/or duration)...." Page 11, lines 3-9. Accordingly, the term "suppressing" is not limited to any single aspect listed above and Applicant is not required to show every aspect listed above. Reduction of RSV viral titer is one aspect of suppressing viral infection. Therefore, the specification provides ample support for suppressing an RSV infection as claimed.

The Examiner also contends that the specification "fails to provide the guidance to use the claimed polynucleotide ISS comprising the sequence (5'-T, C, G-3'), (5'-AACGTTCC-3'), (5'-AACGTTCG-3'), (5' GACGTTCC-3') and (5'-GACGTTCG-3') in the working examples." Office Action, page 3. The Examiner also states that "[b]ecause of the difference in length, a dosage amount of ISS polynucleotide will also vary among different species of mammals." Office Action, page 5. Applicant respectfully disagrees.

Applicant respectfully points out that SEQ ID NO:1 used in the example comprises the sequence 5'-T, C, G-3' and the sequence 5'-AACGTTCG-3'. Applicant notes that the specification describes ISS-containing polynucleotides for use in the invention. See, for example, page 17, line 3 to page 20, line 24. The specification also describes how to make ISS-containing polynucleotides (for example, at page 20, line 25 to page 24, line 28) and how to test such polynucleotides for ISS activity (for example, at page 13, lines 9-16; and page 17, lines 3-10). In addition, the specification describes methods to determine whether a given ISS-containing polynucleotide comprising the sequence 5'-C, G-3' exhibits a suppressing effect on RSV infection as claimed. See, for example, page 30, line 6 to page 35, line 28. Examples 1-3 exemplify administration of a composition comprising an ISS-containing polynucleotide with a 5'-C, G-3' sequence to an animal and measurement of RSV titers in an RSV infected animal. An effective dosage that can be used for a given host and the effectiveness of a claimed ISS-containing polynucleotide with a 5'-C, G-3' sequence can be determined using that described in

the specification and the knowledge of one skilled in the art. Thus, the specification provides adequate guidance pertaining how to use the claimed polynucleotides comprising an ISS.

In addition, the Examiner states that the "state of the art at the time of filing is well known for ISS sequences." Office Action, page 3.

Accordingly, Applicant submits that with the teachings of the specification and knowledge in the art, a person skilled in the art would be able to practice the invention without undue experimentation.

The Examiner contends that the "claims are not enabled for a method that suppresses the infection in all mammals using ISS sequences." Office Action, page 3. The Examiner also states that animal models "such as mouse or rat models do not mimic relevant human conditions" and that "one cannot predict similar results is case of other hosts." Office Action, page 5. Applicant respectfully disagrees.

For a *prima facie* case on non-enablement, the burden is on the Office to demonstrate that there is a reasonable basis to question the presumptively sufficient disclosure made by applicant. See, e.g., *In re Wright*, 27 USPQ2d 1510 (Fed. Cir. 1993); MPEP § 2164.04. In other words, the specification must be taken as being in compliance with the enablement requirement of 35 U.S.C. § 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein. *In re Marzocchi*, 169 USPQ 367, 369 (CCPA 1971). Furthermore, it is incumbent upon the Examiner to explain why one skilled in the art would doubt the truth or accuracy of any statement in a supporting disclosure and to back up these assertions with acceptable and specific evidence. Id. at 370. Absent evidence to the contrary, the specification must be assumed to be enabling.

Applicant respectfully points out that it is a well-established principle of patent law that "patent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art." *In re Vaeck*, 947 F.2d 488, 496 (Fed. Cir. 1991). In *In re Angstadt*, the Court of Customs and Patent Appeals considered the issue of whether section 112 requires

disclosure of a test with every species covered by a claim and concluded that requirement of such a complete disclosure would necessitate a patent application with thousands of examples and "would force an inventor seeking adequate patent protection to carry out a prohibitive number of actual experiments." *In re Angstadt*, 537 F.2d 498, 502 (CCPA 1976). The court concluded that such a requirement would be against public policy because it would have the effect of "depriving inventors of claims which adequately protect them and [would limit] them to claims which practically invite appropriation of the invention while avoiding infringement[, which would] inevitably [have] the effect of suppressing disclosure." Id. at 504. Based on the foregoing, Applicant is not required to disclose a test with every host covered by the claim.

MPEP §2164.02 states that an "*in vivo* animal model example in the specification, in effect, constitutes a "working example" if that example "correlates" with a disclosed or claimed method invention" and that ""[c]orrelation" as used herein refers to the relationship between *in vitro* or *in vivo* animal model assays and a disclosed or a claimed method of use." The same section of MPEP also states that "if the art is such that a particular model is recognized as correlating to a specific condition, then it should be accepted as correlating unless the examiner has evidence that the model does not correlate." Cotton rat model used in this application is an art-accepted model for the study of RSV infection.[1] Therefore, Applicant traverses the contention that enablement in this animal model is insufficient to enable the invention as claimed.

The Examiner cites two publications describing antiviral effect of two compounds, Amantadine and Rimantadine, for respiratory and influenza viral infections to support the contention that "sufficient antiviral effect to provide an alleviation of symptoms related to said virus had not been developed." Office Action, page 3. However, these publications do not support the Examiner's contention. First, the publications are not directed to the use of ISS-

[1] See, for example, specification, page 8, line 27, to page 9, line 2; Wyde *et al.* (1995) *Pediatr. Res.* 38:543-550, abstract (of record).

containing polynucleotides to suppress RSV infection and are thus, not relevant to the present invention. Second, contrary to Examiner's statement, the publications show that several compounds have been developed and demonstrated efficacy in clinical trials. The Examiner cites one of the references as stating that "there is a continuing need for more effective antiviral agents to manage viral acute respiratory infections." Office Action, page 4. A need for the present invention does not mean or support the assertion that the invention is not enabled.

Applicant respectfully submits that the Examiner has not produced any evidence to establish that with the teachings in the specification, a person skilled in the art could not determine an ISS-containing polynucleotide comprising a 5'-C, G-3' sequence exhibiting an effect of suppressing RSV infection as claimed without undue experimentation. As noted by the Examiner on page 4 of the Office Action, the specification provides data that administration of an ISS-containing polynucleotide comprising a 5'-C, G-3' sequence results in suppression of an RSV infection. See, for example, Example 2 and page 40, lines 6-10, of specification. Thus, the Office has failed to establish a *prima facie* case on non-enablement. Applicant's specification provides a presumptively sufficient disclosure providing ample teachings to allow a person skilled in the art to make and/or use the invention without undue experimentation. Applicant respectfully submits that the presently claimed invention is in compliance with enablement requirements.

In view of the above, Applicant respectfully requests withdrawal of this rejection.

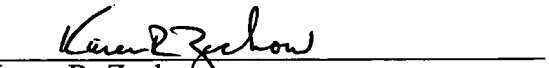
CONCLUSION

Applicant believes that all issues raised in the Office Action have been properly addressed in this response. Accordingly, reconsideration and allowance of the pending claims is respectfully requested. If it is determined that a telephone conversation would expedite the prosecution of this application, the Examiner is encouraged to contact Applicant's representative at the telephone number below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 377882000900.

Respectfully submitted,

Dated: June 24, 2002

By: 

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